BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 943 354 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
22.09.1999 Bulletin 1999/38

(51) Int. Cl.[6]: **A61M 25/00**, A61M 25/10

(21) Application number: **99104299.5**

(22) Date of filing: **03.03.1999**

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **17.03.1998 US 40505**

(71) Applicant: **MEDTRONIC, INC.**
Minneapolis, Minnesota 55432-3576 (US)

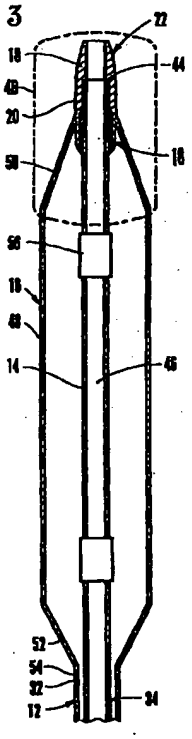
(72) Inventors:
- **Fugoso, Mauricio L.**
  Chula Vista, California 91910 (US)
- **Rowean, Karen M.**
  San Diego, California 92128 (US)
- **Fourmont, Michelle E.**
  Carlsbad, California 92008 (US)
- **Brahana, Christopher Todd**
  San Diego, California 92111 (US)
- **Schwab, Sharon Ma**
  San Diego, California 92117 (US)
- **Minas, Maritess E.**
  San Diego, California 92139 (US)

(74) Representative:
Hughes, Andrea Michelle
Frank B. Dehn & Co.,
European Patent Attorneys,
179 Queen Victoria Street
London EC4V 4EL (GB)

(54) Balloon attachment at catheter tip

(57) An intravascular medical catheter 10 and method of manufacturing a medical catheter are provided herein. The medical catheter includes a guidewire shaft 14, a sleeve 18, and a balloon 16. The sleeve is attached to the guidewire shaft while a distal tail 20 of the balloon is thermally bonded to the sleeve. Because of the sleeve, the distal tail of the balloon can be thermally bonded even if the guidewire shaft is made of a material which is thermally incompatible with the balloon. Thus, for example, a medical catheter can be made with an HDPE guidewire shaft and a balloon made of PEBA, PET, Polyurethane, or Nylon. The resulting medical catheter has a catheter tip which is durable, flexible, and has a relatively low profile for good tracking in the body vessel and good lesion crossing.

Fig. 3



EP 0 943 354 A1

Description

[0001] The present invention relates to an intravascular medical catheter and a method of manufacturing an intravascular medical catheter. More specifically, the present invention relates to a medical catheter having good guidewire movement and tracking, as well as good tip flexibility and durability.

[0002] Percutaneous transluminal coronary angioplasty (hereinafter "angioplasty") is a procedure used to treat a stenosis within a body vessel of a human being. A medical catheter having an inflatable balloon attached to a catheter shaft and a guidewire shaft is commonly used during the angioplasty procedure. First, the guidewire shaft and balloon are advanced over a guidewire which is positioned within the body vessel until the balloon is adjacent to the stenosis. Subsequently, the balloon is inflated. This causes the site of the stenosis to compress into the arterial wall and the body vessel to dilate.

[0003] In recent years, there has been a continuing effort to improve the performance characteristics of medical catheters. Unfortunately, the design of most existing medical catheters has always involved trading off various performance characteristics. For example, many physicians prefer the guidewire movement/tracking of a guidewire shaft made of high density polyethylene ("HDPE") instead of a guidewire shaft made of Polyether Block Amide ("PEBA"), Polyethylene Terephthalate ("PET"), or Nylon. However, a balloon made of HDPE, in many instances, may not have satisfactory inflation or pressure characteristics. In fact, for some applications, balloons made of PEBA, PET, or Nylon provide superior inflation and pressure characteristics. Because PEBA, PET, and Nylon can not be thermally bonded to HDPE, it is often necessary to use an adhesive to bond a PEBA, PET, or Nylon balloon to a HDPE guidewire shaft. Unfortunately, the adhesive bond at the catheter tip has a relatively large profile, and is relatively stiff. As a result thereof the medical catheter is relatively difficult to manoeuvre because the catheter tip does not track well in the body vessel.

[0004] One attempt to solve this problem involves utilizing the same or thermally compatible materials for the guidewire shaft and the balloon, so that the balloon can be thermally bonded to the guidewire shaft. The thermal bonding results in a high strength, durable, flexible, transitionless, and low profile catheter tip. For example, Guidant, located in Temecula, California, manufactures a medical catheter having a balloon and guidewire shaft which are made of nylon. However, this device is not entirely satisfactory because physicians typically prefer a guidewire shaft made of HDPE.

[0005] Another attempt to solve this problem involves the co-extrusion of the guidewire shaft with an inner tube made of HDPE and an outer shell made of nylon. Subsequently, a nylon balloon can be thermally bonded to the nylon outer shell. Unfortunately, the co-extruded guidewire shaft can be more difficult to manufacture and delamination of the co-extruded guidewire shaft may occur.

[0006] In light of the above, it is an object of the present invention to provide an improved medical catheter which utilizes a guidewire shaft made of HDPE regardless of the material utilized for the inflatable balloon. Another object of the present invention is to provide a medical catheter having good guidewire movement and tracking, as well as a catheter tip having a low profile, and good strength, flexibility and durability characteristics. Still another object of the present invention is to provide a medical catheter having a distal tail which is thermally bonded and transitionless.

[0007] The present invention is directed to a medical catheter useful for an angioplasty procedure which satisfies these objectives.

[0008] According to a first aspect, the present invention provides a medical catheter adapted for use within a body vessel with a guidewire, the medical catheter comprising:

a guidewire shaft having a guidewire lumen which is adapted to receive the guidewire; and
an inflatable balloon having a distal tail; characterised by
a sleeve attached to the guidewire shaft; and wherein
the inflatable balloon distal tail is thermally bonded to the sleeve to attach the distal tail of the balloon to the sleeve.

[0009] According to a second aspect, there is provided a method for manufacturing a medical catheter which is adapted to be inserted within a body vessel, the method comprising the steps of:

providing a guidewire shaft having a guidewire lumen (46) which is adapted to receive a guidewire;
attaching a sleeve to the guidewire shaft; and
thermally bonding a distal tail of an inflatable balloon to the sleeve to sealingly affix the distal tail to the sleeve.

[0010] As provided in detail below, the thermal bonding of the distal tail of the balloon to the sleeve results in a high strength, low profile, flexible, and transitionless catheter tip. Further, because of this unique design, a guidewire shaft made of HDPE can be utilized regardless of the material utilized for the balloon. Therefore, the material utilized for the guidewire shaft and the material utilized for the inflatable balloon can be particularly tailored to suit the preferences of the physician.

[0011] As used herein, the term "thermal bonding" shall mean the bonding of two mated polymer materials, upon the application of heat. The term "thermally compatible" shall mean the condition where two mated polymer materials, upon the application of heat, bond

together with no discernible interface, i.e., they are miscible. Polymers which are identical are thermally compatible. However, the polymers do not have to be identical to be thermally compatible. For example, a higher durometer material is thermally compatible to a lower durometer of the same material.

[0012] As used herein, the term "thermally incompatible" shall mean the condition where two mated polymer materials, upon the application of heat, form distinct phases at their interface and crystallize independently of each other.

[0013] Because of the sleeve, the catheter tip can be thermally bonded, even though the guidewire shaft is made of a guidewire shaft material which is not thermally compatible with a balloon material which is utilized for the balloon. For example, the guidewire shaft material can be a high density polyethylene ("HDPE") while the balloon material and the sleeve material can be PEBA, PET, Nylon, Polyurethane, or blends thereof. As the result of the thermal bond between the sleeve and the balloon, the balloon is easier to move in the body vessel, commonly referred to herein as "improved tracking." Further, the inflatable balloon is easier to move past the lesion in the vessel, commonly referred to as "improved lesion crossing characteristics."

[0014] In one embodiment of the present invention, an adhesive is positioned between the guidewire shaft and the sleeve to sealingly affix the sleeve to the thermally incompatible guidewire shaft. In a second embodiment of the present invention, the sleeve is compression bonded to the thermally incompatible guidewire shaft. In the second embodiment, because the sleeve and the guidewire shaft are thermally incompatible, heating of the sleeve and guidewire shaft merely results in the sleeve being compressed against the guidewire shaft. In this embodiment, an adhesive can cover the proximal end of the sleeve and a portion of the guidewire shaft to inhibit peeling of the sleeve away from the guidewire shaft.

[0015] In a third embodiment, the guidewire shaft and sleeve are thermally compatible and the sleeve can be thermally bonded to the guidewire shaft. In this embodiment, the sleeve and guidewire shaft can be made of a polymer having a different durometer. For example, a lower durometer material can be used for the sleeve while a higher durometer of the same material can be used for the guidewire shaft. Therefore, the sleeve is more flexible than the guidewire shaft. The resulting medical catheter has a flexible catheter tip to enhance tracking and lesion crossing, and a guidewire shaft with appropriate column strength.

[0016] Importantly, the medical catheter provided herein has good guidewire movement and tracking, good vessel tracking and lesion crossing characteristics, and good tip strength and durability characteristics.

[0017] The novel features of this invention, as well as the invention itself, both as to its structure and its operation, will be best understood from the accompanying drawings, taken in conjunction with the accompanying description, given by way of example only, and in which similar reference characters refer to similar parts, and in which:

Figure 1 is a perspective view, in partial cutaway, of a medical catheter having features of the present invention;

Figure 2 is a perspective view of the medical catheter positioned within a patient;

Figure 3 is a cross-sectional view of a portion of one embodiment of the medical catheter;

Figure 4A is an enlarged, cross-sectional assembly view of the medical catheter of Figure 3;

Figure 4B is an enlarged, cross-sectional view of the medical catheter taken from Figure 3;

Figure 5A is an enlarged, cross-sectional assembly view of a portion of a second embodiment of a medical catheter having features of the present invention;

Figure 5B is an enlarged, cross-sectional view of a portion of the medical catheter of Figure 5A;

Figure 6A is an enlarged, cross-sectional assembly view of a portion of a third embodiment of a medical catheter having features of the present invention; and

Figure 6B is an enlarged, cross-sectional view of a portion of the medical catheter of Figure 6A.

[0018] Referring to Figure 1, a medical catheter 10 having features of the present invention includes a catheter shaft 12, a guidewire shaft 14, an inflatable balloon 16, and a tubular sleeve 18 (shown in phantom in Figure 1). As provided in detail below, the tubular sleeve 18 fits over a portion of the guidewire shaft 14 and is thermally bonded to a distal tail 20 of the inflatable balloon 16. Because the balloon 16 is thermally bonded to the sleeve 18 instead of bonded with an adhesive 60 to the guidewire shaft 14, a tip 22 of the medical catheter 10 has a lower profile and better strength, durability, and flexibility characteristics. Further, because of the sleeve 18, the medical catheter 10 can utilize a guidewire shaft 14 made of HDPE for preferred movement and tracking over a guidewire 24 (shown in Figure 2) with a thermally incompatible balloon 16.

[0019] As illustrated in Figure 2, a portion of the medical catheter 10 and the guidewire 24 can be positioned in a body vessel 26 of a patient 28 during an angioplasty procedure. The location of entry into the patient 28 and the location of the inflatable balloon 16 illustrated in Figure 2 is merely exemplary.

[0020] The catheter shaft 12 is used by the physician to position the inflatable balloon 16 within the body vessel 26 and transfer an inflation fluid (not shown) to the inflatable balloon 16. In the embodiment shown in Figure 1, the catheter shaft 12 includes a catheter shaft proximal end 30, a catheter shaft distal end 32, and an inflation lumen 34 in fluid communication with the bal-

loon 16. A manifold 36 having an inflation/deflation port 38 and a guidewire port 40 is secured to the catheter shaft proximal end 30. The inflation/deflation port 38 is in fluid communication with the inflation lumen 34 while the guidewire port 40 is connected to the guidewire shaft 14. In the embodiments illustrated in the Figures, the inflatable balloon 16 is secured to the catheter shaft distal end 32. Further, the catheter shaft 12 encircles and is substantially coaxial with the guidewire shaft 14.

[0021] Preferably, the catheter shaft 12 is made of a material which is thermally compatible with the balloon 16 so that the balloon 16 can be thermally bonded to the catheter shaft 12. For example, the catheter shaft 12 can be manufactured by extruding a polymer such as PEBA, PET, Polyurethane, PE, or Nylon.

[0022] The guidewire shaft 14 includes a guidewire shaft proximal end (not shown), a guidewire shaft distal end 44 (shown in Figures 3-5), and a guidewire lumen 46. The guidewire shaft proximal end is connected to the guidewire port 40, while the guidewire shaft distal end 44 is attached to the tubular sleeve 18. The guidewire lumen 46 is sized and shaped to receive the guidewire 24. A guidewire shaft 14 having a 0.425 mm (0.017 inch) inner diameter and a 0.575 mm (0.023 inch) outer diameter is suitable for a standard 3.5 mm (0.14 inch) guidewire 24.

[0023] Typically, the guidewire shaft 14 is made by extruding a guidewire shaft material. Presently, the preferred guidewire shaft material is High Density Polyethylene ("HDPE") which provides excellent movement and tracking of the guidewire shaft 14 over the guidewire 24. Alternatively, for example, a Low Density Polyethylene ("LDPE") with an additive, or an HDPE/LDPE blend can be utilized for the guidewire shaft 14.

[0024] The balloon 16 can be used to dilate the body vessel 26 and/or position a stent (not shown) within the body vessel 26. The balloon 16 includes a body section 48 which separates a distal cone section 50 from a proximal cone section 52. Prior to assembly, the inflatable balloon 16 includes a proximal tail 54 which can be thermally bonded to the catheter shaft 12 and the distal tail 20 which is thermally bonded to the sleeve 18. Alternatively, the proximal tail 54 can be bonded with an adhesive to the catheter shaft 12. Typically, the balloon size for use in a body vessel 26 ranges from between approximately five millimetres to fifty millimetres (5 mm-50 mm) in length and between approximately one and one-half millimetres to five millimetres (1.5 mm-5.0 mm) in diameter.

[0025] The balloon 16 can be manufactured by initially extruding a balloon material to form a tube. Subsequently, the tube is heated above its glass transition temperature and radially expanded within a blow mold (not shown) to form the balloon 16. Preferred balloon materials include PEBA, PET, PE, Polyurethane, Nylon, or blends thereof because balloons made from these materials have excellent inflation and rewrap characteristics. It is important to note that PEBA, PET, Polyurethane, and Nylon are thermally incompatible with HDPE.

[0026] The tubular sleeve 18 sealingly attaches to the guidewire shaft 14 and sealingly attaches the distal tail 20 to the guidewire shaft 14. Preferably, the sleeve 18 is made of a sleeve material which is thermally compatible with the balloon material so that the sleeve 18 can be thermally bonded to the distal tail 20 of the balloon 16. For example, the tubular sleeve 18 can be manufactured by extruding a polymer such as PEBA, PET, PE, Polyurethane, Nylon, or blends thereof. The sleeve material is also chosen based upon the desired catheter tip 22 stiffness and strength. The sleeve material should be thermally compatible to the balloon material and does not have to be identical to the balloon material.

[0027] With the teaching provided herein, those skilled in the art will recognize alternative ways to manufacture the catheter shaft 12, the guidewire shaft 14, the balloon 16, and the sleeve 18 and that alternative materials can be utilized for these components.

[0028] A cross-sectional view of a portion of a first embodiment of the medical catheter 10 is illustrated in Figure 3. In this embodiment, the proximal tail 54 of the balloon 16 is thermally bonded to the catheter shaft 12. Further, a pair of spaced apart, tubular, radiopaque markers 56 can be bonded to the guidewire shaft 14 to facilitate proper positioning of the inflatable balloon 16 in the body vessel 26.

[0029] Figures 4A and 4B each illustrate an enlarged view of the catheter tip 22 of the embodiment shown in Figure 3. More specifically, Figure 4A shows the catheter tip 22 during assembly, prior to thermal bonding, while Figure 4B shows the catheter tip 22 after thermal bonding. In this embodiment, a sleeve proximal end 58 is attached with an adhesive 60 to the guidewire shaft distal end 44. The adhesive 60 is positioned between the sleeve 18 and the guidewire shaft 14 to sealingly attach the sleeve 18 to the guidewire shaft 14. A suitable adhesive 60 is sold under the trade name Loctite® 3311 U.V. by Loctite® Corporation located in Hartford, Connecticut. Suitable alternative adhesives include Loctite® 3321 U.V. and Loctite® 420 Cyanoacrylate sold by Loctite® Corporation or UR-0531 Urethane adhesive sold by H.B. Fuller located in St. Paul, Minnesota.

[0030] With reference to Figure 4A, an outer diameter of the guidewire shaft 14 includes a necked down section 62 proximal to the guidewire shaft distal end 44 and an inner surface of the sleeve 18 includes a corresponding thick walled section 64. The necked down section 62 of the guidewire shaft 14 has a smaller outer diameter than the rest of the guidewire shaft 14 while the thick walled section 64 has a smaller inner diameter than the rest of the sleeve 18. This allows the thick walled section 64 to be attached to the distal tail 54 while minimizing the profile of the catheter tip 22.

[0031] In the embodiment shown in Figure 4A, the

sleeve 18 encircles only between approximately one-half millimetre (0.5 mm) and fifteen millimetres (15 mm) of the guidewire shaft 14 and more preferably between one-half millimetre (0.5 mm) to two millimetres (2.0 mm), to minimize the profile of the medical catheter 10 and stiffness related to the bond. Preferably, a sleeve distal end 66 extends past the guidewire shaft distal end 44 to minimize the profile of the medical catheter 10 and stiffness at the catheter tip 22 related to the bond. For example, the sleeve distal end 66 can extend past the guidewire shaft distal end 44 between approximately one-half millimetre (0.5 mm) and five millimetres (5.0 mm). Alternatively, the sleeve distal end 66 can be substantially even with the guidewire shaft distal end 44. If the sleeve 18 extends past the guidewire shaft 14, the sleeve distal end 66 can be formed to have substantially the same inner diameter as the guidewire lumen 46 during thermal bonding to the distal tail 20 of the balloon 16.

[0032] Figure 4B illustrates the sleeve distal end 66 attached to the distal tail 20 of the balloon 16 with thermal bonding. The thermal bond causes the sleeve 18 and the distal tail 20 to appear as a single, unitary component. The resulting thermal bond is relatively strong, transitionless, flexible, and durable. Additionally, the thermal bond has a low profile for improved tracking and lesion crossing in the vessel 26. Further, the catheter tip 22 can be tapered for improved tracking and lesion crossing.

[0033] Figures 5A and 5B each illustrate an enlarged view of a second embodiment of the catheter tip 22. More specifically, Figure 5A shows the catheter tip 22 prior to thermal bonding, while Figure 5B shows the catheter tip 22 after thermal bonding between the sleeve 18 and the balloon 16. In this embodiment, if the sleeve 18 and the guidewire shaft 14 are thermally incompatible, the tubular sleeve 18 can be compression bonded to the guidewire shaft 14. Further, an adhesive 60 can cover a portion of the guidewire shaft 14 and an outer surface of the sleeve proximal end 58 to prevent peeling of the sleeve 18 from the guidewire shaft 14. Suitable adhesives 60 include Loctite® 420 Cyanoacrylate, Loctite® 3311, or Loctite® 3321 sold by Loctite® Corporation, or U.R.-0531 sold by H.B. Fuller located in St. Paul, Minnesota.

[0034] Referring back to Figure 5A, the sleeve 18 can include a sleeve shaft section 68 which encircles the guidewire shaft 14 and a sleeve tail section 70 which fits within the distal tail 20 of the balloon 16. In this embodiment, the inner diameter of sleeve shaft section 68 is larger than the inner diameter of the sleeve tail section 70. This allows the sleeve shaft section 68 to fit over the guidewire shaft 14 while the sleeve tail section 70 has substantially the same inner diameter as the guidewire lumen 46. The sleeve shaft section 68 encircles between approximately one millimetre (1.0 mm) and fifteen millimetres (15 mm) of the guidewire shaft 14, and more preferably between two millimetres (2.0 mm) to three millimetres (3.0 mm) to minimize the profile and stiffness related to bond. Preferably, the sleeve distal end 66 extends past the guidewire shaft distal end 44 to minimize the profile of the medical catheter 10 and stiffness at the catheter tip 22 related to the bond. For example, the sleeve distal end 66 can extend past the guidewire shaft distal end 44 between approximately one-half millimetre (0.5 mm) and five millimetres (5.0 mm). Alternatively, the sleeve distal end 66 can be substantially even with the guidewire shaft distal end 44. If the sleeve 18 extends past the guidewire shaft 14, the sleeve distal end 66 can be formed to have substantially the same inner diameter as the guidewire lumen 46 during thermal bonding to the distal tail 20 of the balloon 16.

[0035] Referring to Figure 5B, the thermal bonding causes the tubular sleeve 18 and the distal tail 20 to appear as a single, homogenous component. The resulting thermal bond is relatively strong, transitionless, durable, and flexible and has a low profile to allow for improved tracking and lesion crossing. Further, as shown in Figure 5B, the sleeve 18 merely contacts the guidewire shaft 14 as a result of the compression bond. Additionally, the catheter tip 22 can be tapered for improved tracking and lesion crossing.

[0036] Figures 6A and 6B each illustrate an enlarged view of a third embodiment of the catheter tip 22. Figure 6A shows the catheter tip 22 prior to thermal bonding, while Figure 6B shows a catheter tip 22 after thermal bonding of the guidewire shaft 14 to the sleeve 18, and the sleeve 18 to the balloon 16. In this embodiment, the guidewire shaft 14, the sleeve 18, and the balloon 16 are all thermally compatible. Even though the balloon 16 and the guidewire shaft 14 are thermally compatible, it is desirable in many instances, to utilize a sleeve 18 which is more flexible than the guidewire shaft 14. This embodiment is particularly useful for joining a sleeve 18 made of a lower durometer material to a guidewire shaft 14 made of a higher durometer of the same material. For example, the guidewire shaft 14 could be made out of a high density HDPE, while the sleeve 18 is made from a LDPE which is more flexible. Another example would be a guidewire shaft 14 made of Pebax 7233 and a sleeve 18 made of Pebax 7033. Pebax is a PEBA sold by Elf Atochem North America, located in Philadelphia, Pennsylvania. In either example, the resulting medical catheter 10 has a more flexible catheter tip 22 for improved tracking and lesion crossing. Further, because the guidewire shaft 14 is thermally bonded to the sleeve 18 and the sleeve 18 is thermally bonded to the balloon 16, the catheter tip 22 is transitionless.

[0037] In the embodiment shown in Figure 6A, prior to thermal bonding, the sleeve 18 includes the sleeve shaft section 68 which encircles the guidewire shaft 14 and the sleeve tail section 70 which fits within the distal tail 20 of the balloon 16. After assembly, as illustrated in Figure 6B, thermal bonding causes the guidewire shaft 14, the tubular sleeve 18, and the distal tail 20 to appear

as a single, homogeneous component. The resulting thermal bond is relatively strong, transitionless, durable, flexible, and has a profile for improved tracking and lesion crossing. Additionally, in this embodiment, the catheter tip 22 can be tapered for improved tracking and lesion crossing.

[0038] Importantly, the thermal bonding of the distal tail 20 to the tubular sleeve 18 allows the medical catheter 10 provided herein to have a low profile. This results in improved tracking and lesion crossing characteristics. Further, the thermal bond is stronger, more durable, and more flexible than an adhesive bond. Additionally, because of the unique design provided herein, the medical catheter 10 can utilize a HDPE guidewire shaft 14 for preferred guidewire 24 movement and tracking with a thermally incompatible balloon material.

Claims

1. A medical catheter adapted for use within a body vessel with a guidewire, the medical catheter comprising:

   a guidewire shaft (14) having a guidewire lumen (46) which is adapted to receive the guidewire (24); and
   an inflatable balloon (16) having a distal tail (20); characterised by
   a sleeve (18) attached to the guidewire shaft (14); and wherein
   the inflatable balloon distal tail (20) is thermally bonded to the sleeve (18) to attach the distal tail (20) of the balloon (16) to the sleeve (18).

2. The medical catheter of claim 1 wherein the sleeve (18) is tubular and encircles only a portion of the guidewire shaft (14).

3. The medical catheter of claim 1 or 2, wherein the sleeve (18) includes a sleeve distal end (66) which extends past a guidewire shaft distal end (44) of the guidewire shaft.

4. The medical catheter of any preceding claim, wherein the guidewire shaft (14) is made of a guidewire shaft material which is thermally incompatible with a balloon material which is utilized in the balloon (16).

5. The medical catheter of any preceding claim, wherein the sleeve (18) is made of a sleeve material which is thermally compatible with the balloon material and thermally incompatible with the guidewire shaft material.

6. The medical catheter of claim 5 wherein the balloon material is selected from a group consisting of PEBA, PET, Polyurethane, and Nylon and the sleeve material is selected from a group consisting of PEBA, PET, Polyurethane, and Nylon.

7. The medical catheter of claim 4, 5 or 6 wherein the guidewire shaft material includes polyethylene.

8. The medical catheter of any preceding claim, wherein the sleeve (18) is compression bonded to the guidewire shaft (14).

9. The medical catheter of any preceding claim, including an adhesive (60) for attaching the sleeve (18) to the guidewire shaft (14).

10. The medical catheter of claim 9 wherein the adhesive (60) is positioned between the guidewire shaft (14) and the sleeve (18).

11. The medical catheter of claim 9 or 10, wherein said adhesive covers a sleeve proximal end (58) of the sleeve and a portion of the guidewire shaft to inhibit peeling of the sleeve away from the guidewire shaft.

12. The medical catheter of any of claims 1 to 7, wherein the sleeve (18) is thermally bonded to the guidewire shaft (14) and the sleeve is made of a sleeve material which is thermally compatible with the balloon (16).

13. The medical catheter of any preceding claim, further comprising:

   a catheter shaft (12) defining an inflation lumen, the catheter shaft encircling a portion of the guidewire shaft (14); and wherein
   said inflatable balloon (16) has a proximal tail (54) which is bonded and sealingly affixed to the catheter shaft (12) and said distal tail (20) is thermally bonded and sealingly affixed to said sleeve (18).

14. A method for manufacturing a medical catheter which is adapted to be inserted within a body vessel, the method comprising the steps of:

   providing a guidewire shaft (14) having a guidewire lumen (46) which is adapted to receive a guidewire (24);
   attaching a sleeve (18) to the guidewire shaft; and
   thermally bonding a distal tail (20) of an inflatable balloon (16) to the sleeve to sealingly affix the distal tail to the sleeve (18).

15. The method of claim 14 wherein the step of providing a guidewire shaft (14) includes providing a guidewire shaft made of a guidewire shaft material which is thermally incompatible with a balloon

material which is utilized in the balloon (16) and a sleeve material which is utilized in the sleeve (18).

16. The method of claim 14 or 15 wherein the step of attaching a sleeve (18) includes the steps of compression bonding the sleeve to the guidewire shaft (14) and applying an adhesive (60) over a portion of an outer surface of the sleeve and a portion of the guidewire shaft to inhibit peeling of the sleeve away from the guidewire shaft.

17. The method of claim 16 wherein the step of attaching a sleeve (18) includes the step of applying an adhesive (60) between the guidewire shaft (14) and the sleeve to attach the sleeve to the guidewire shaft.

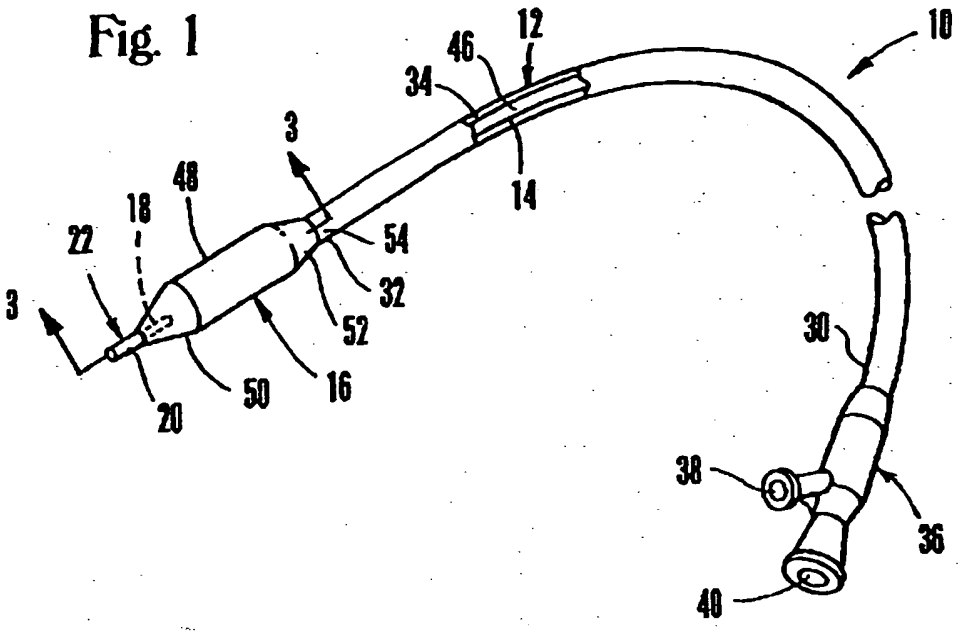
18. The method of claim 14 wherein the step of attaching a sleeve (18) includes the step of thermally bonding the sleeve (18) to the guidewire shaft (14).

19. The method of any of claims 14 to 18, wherein the step of attaching a sleeve (18) comprises attaching a tubular sleeve (18) to the guidewire shaft (14) such that the tubular sleeve encircles only a portion of the guidewire shaft.

20. The method of any of claims 14 to 19, further including the steps of:

providing a catheter shaft (12) which encircles a portion of the guidewire shaft; and
bonding a proximal tail (54) of the inflatable balloon (16) to the catheter shaft to sealingly affix the proximal tail to the catheter shaft.

Fig. 1



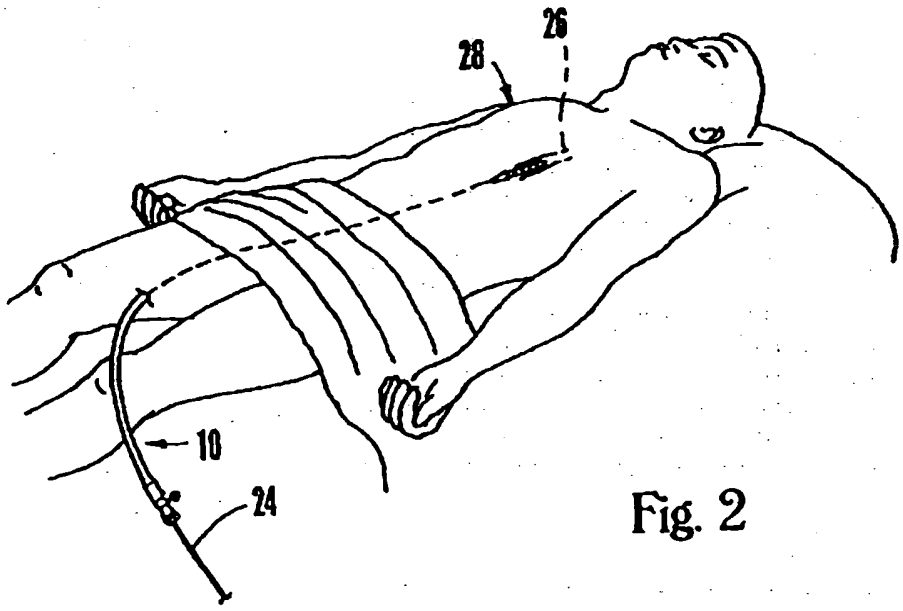


Fig. 2

Fig. 3

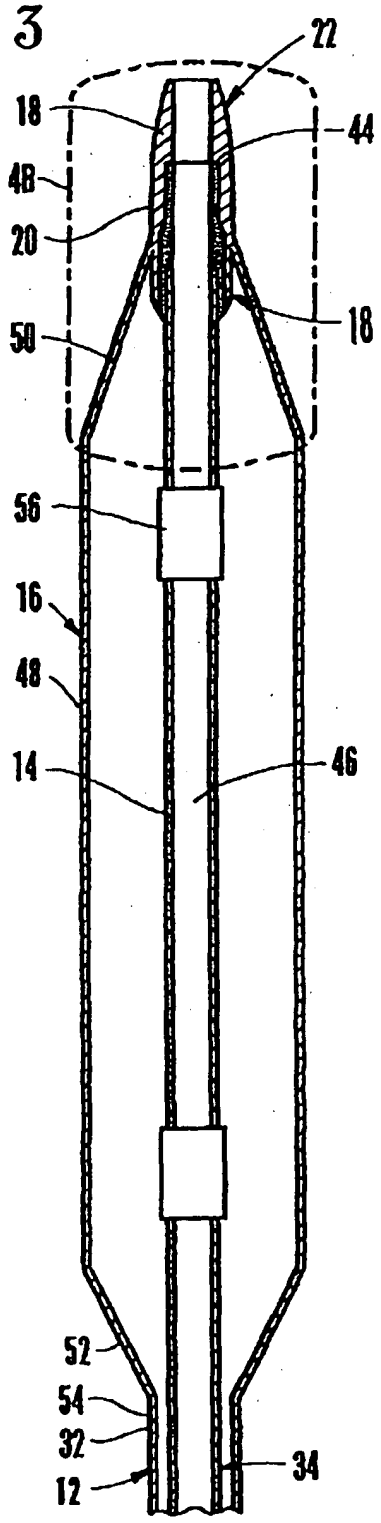


Fig. 4A

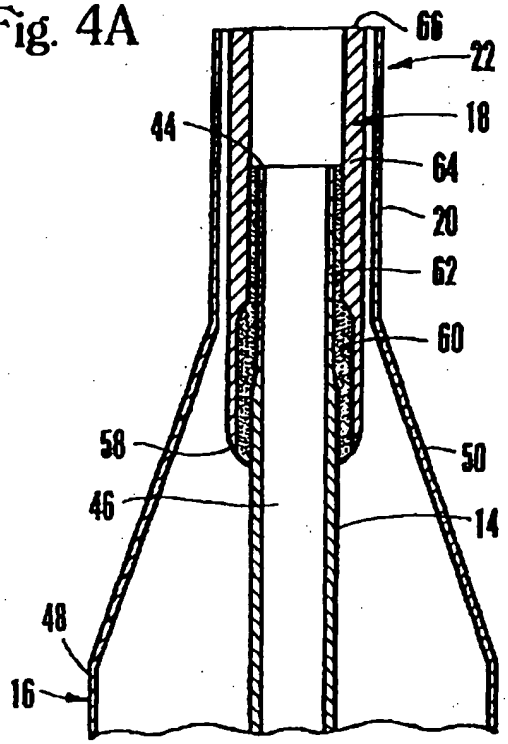
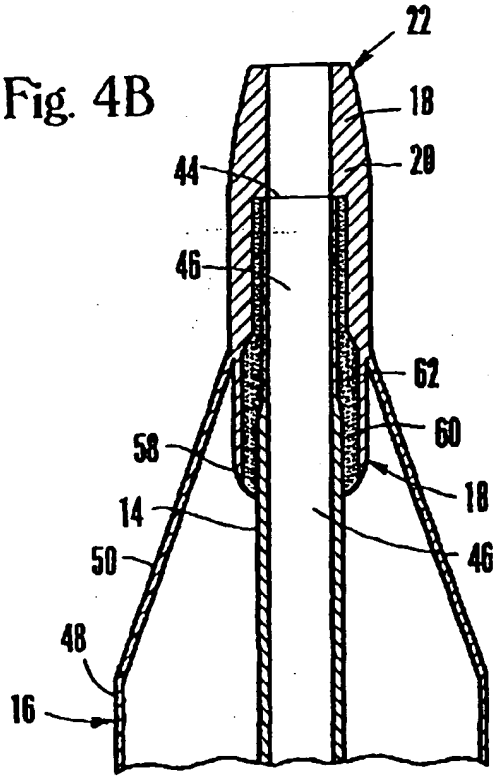


Fig. 4B



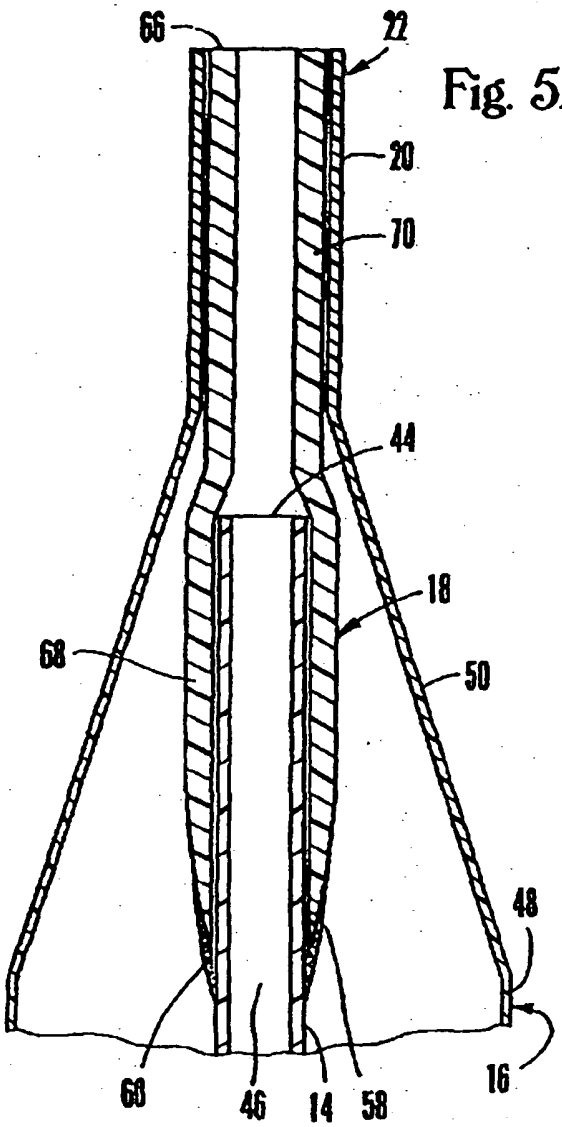

66
22
20
70
44
18
68
50
48
68
46
14
58
16

Fig. 5A

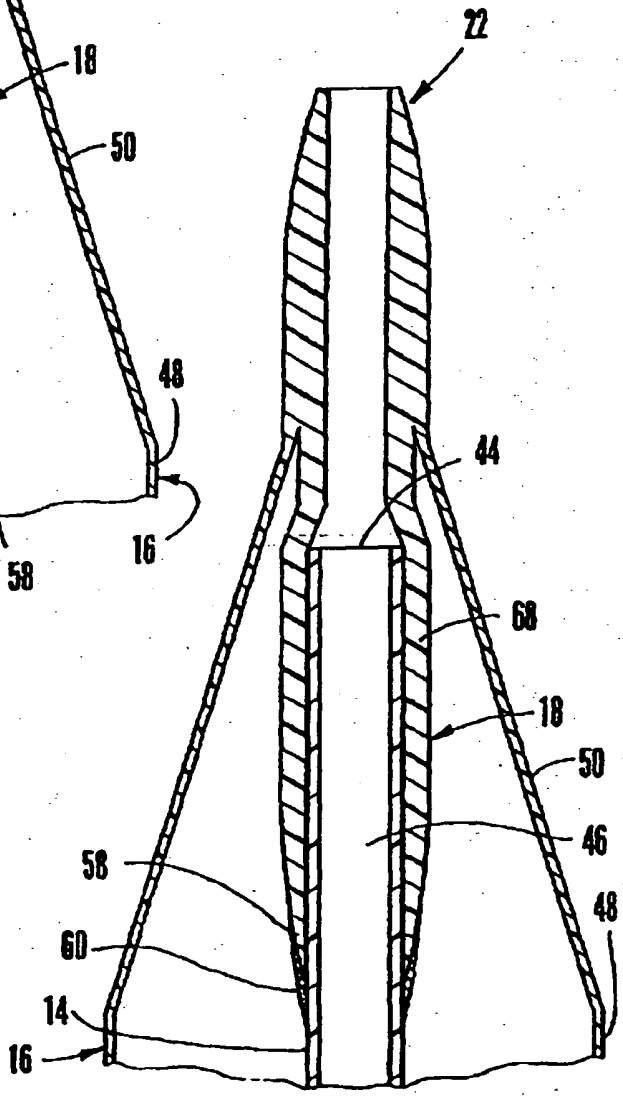

22
44
68
18
50
46
58
48
60
14
16

Fig. 5B

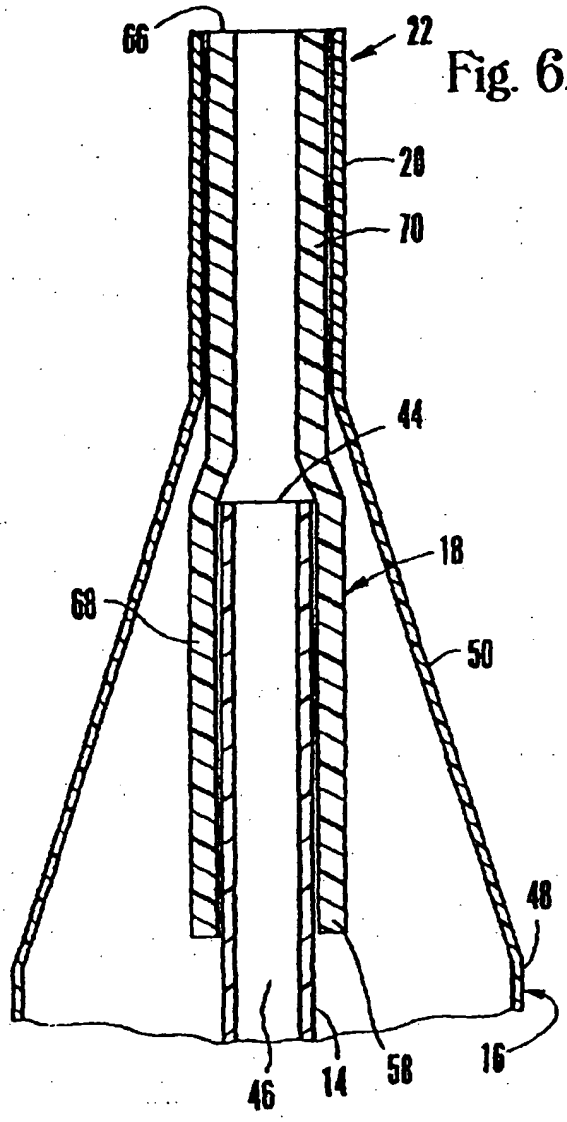


Fig. 6A

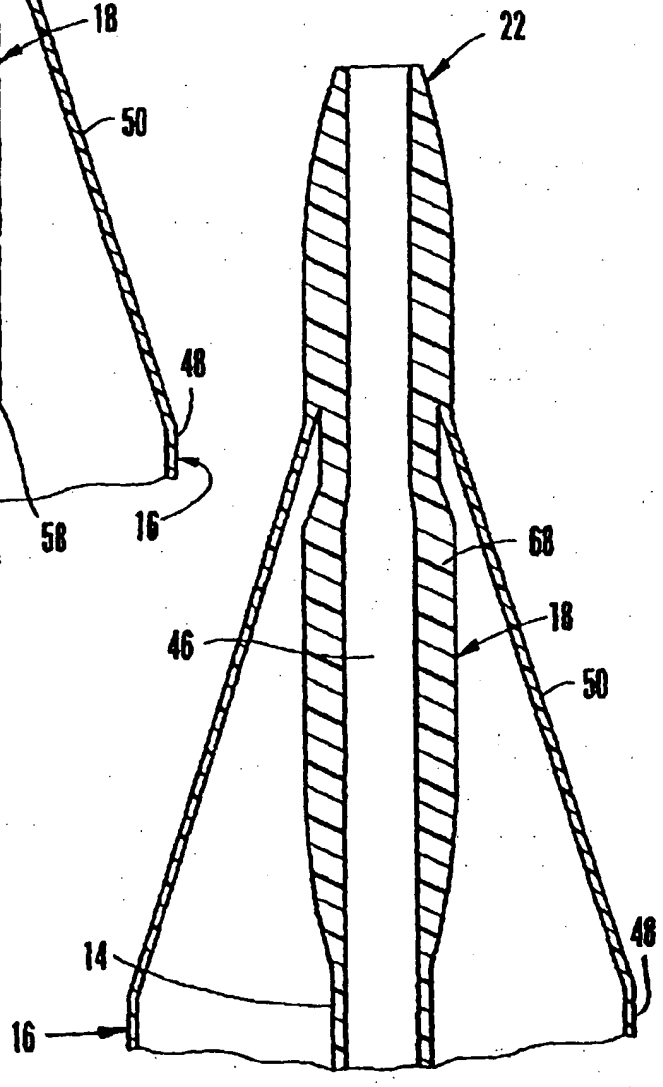


Fig. 6B

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 99 10 4299

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	US 5 460 607 A (MIYATA ET AL.) 24 October 1995 * column 7, line 26 - line 58 * * figures 1,14 *	1-3,9, 10,13, 14,17, 19,20	A61M25/00 A61M25/10
Y		4,5,7,8, 15	
A		6	

Y	US 4 055 187 A (PATEL ET AL.) 25 October 1977 * column 3, line 30 - column 4, line 47 * * figure 2 *	4,5,7,8, 15	

X	WO 89 02763 A (LEOCOR, INC.) 6 April 1989 * page 9, line 24 - page 11, line 30 * * page 13, line 17 - line 20 * * page 14, line 34 - line 35 * * figure 1 *	1-4	
A		6	TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A	US 4 913 701 A (TOWER) 3 April 1990 * the whole document *	4-9,16	A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	28 June 1999	Schönleben, J

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 99 10 4299

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

28-06-1999

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5460607 A	24-10-1995	JP 6114108 A	26-04-1994
		JP 6114109 A	26-04-1994
		JP 2770689 B	02-07-1998
		JP 6165821 A	14-06-1994
		JP 2795111 B	10-09-1998
		JP 6165820 A	14-06-1994
		FR 2696098 A	01-04-1994
		FR 2701654 A	26-08-1994
		US 5683347 A	04-11-1997
		IT 1272697 B	26-06-1997
US 4055187 A	25-10-1977	AU 508294 B	13-03-1980
		AU 2754077 A	08-02-1979
		BE 857558 A	01-12-1977
		BR 7704825 A	28-03-1978
		CA 1096732 A	03-03-1981
		DE 2734701 A	09-02-1978
		FR 2360318 A	03-03-1978
		GB 1522790 A	31-08-1978
		GB 1522789 A	31-08-1978
		JP 53020688 A	25-02-1978
		JP 62009344 B	27-02-1987
		NL 7708289 A	07-02-1978
		NZ 184681 A	11-12-1979
		SE 7708575 A	06-02-1978
		US 4154243 A	15-05-1979
		US 4188954 A	19-02-1980
		ZA 7704305 A	28-06-1978
WO 8902763 A	06-04-1989	US 4921483 A	01-05-1990
		AT 106761 T	15-06-1994
		AU 2543288 A	18-04-1989
		CA 1323273 A	19-10-1993
		CN 1036333 A	18-10-1989
		DE 3850116 D	14-07-1994
		DE 3850116 T	15-09-1994
		DK 74690 A	22-03-1990
		EP 0383794 A	29-08-1990
		EP 0597465 A	18-05-1994
		JP 2501712 T	14-06-1990
		JP 5011996 B	16-02-1993
		US 5066282 A	19-11-1991
		US 5158540 A	27-10-1992
US 4913701 A	03-04-1990	NONE	

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82